Title: Effects of a pulmonary rehabilitation program with balance training on patients with COPD

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Structured Abstract

Purpose: Patients with Chronic Obstructive Pulmonary Disease (COPD) have balance impairments however, pulmonary rehabilitation (PR) has only minor improvements in functional balance. Therefore, there is a need to explore balance training within PR interventions. This study aimed to assess the effects of a PR program with a specific component of balance training on functional balance of patients with COPD.

Methods: Twenty-two outpatients with COPD (68.0±11.8yrs; forced expiratory volume in 1 second 72.2±22.3% predicted) participated in a 12-week PR program with exercise training (3*week) and psychoeducation (1*week). Exercise training sessions comprised endurance, strength and a specific component of balance training. Timed Up and Go (TUG) test was used to assess functional balance before/after the PR. Health-related quality of life (St. George's Respiratory Questionnaire, SGRQ), quadriceps muscle strength (10 repetition maximum) and exercise tolerance (6-minute walk test) were also assessed.

Results: Patients had significant improvements in TUG scores after PR (mean change -1.7±1.4s; p=0.001; effect size=1.249). Before PR, 9(41%) participants and after PR only 1(4.5%) had a TUG performance worse than the average performance of age-matched healthy peers (p=0.008). The SGRQ symptoms score (p=0.012), quadriceps muscle strength (p=0.001) and exercise tolerance (p=0.001) were also improved after PR.

Conclusions: Pulmonary rehabilitation with a specific component of balance training had a large effect on functional balance of patients with COPD. These findings highlight the importance of including balance training in PR programs. Further research is needed to determine the optimal intervention to improve balance and its specific components among patients with COPD.

Condensed Abstract

This study assessed the effects of a pulmonary rehabilitation (PR) program with a specific component of balance training on functional balance of patients with COPD. The results suggest that balance training should be included in PR programs. Further research is needed to determine the optimal intervention to improve patients' balance.

Keywords: Chronic obstructive lung disease; Functional balance; Rehabilitation; Risk of falling.

Introduction

Patients with Chronic obstructive pulmonary disease (COPD) present impairments in exercise tolerance, muscle strength in both upper and lower extremities, self-reported functioning, but also in balance.[1] Moreover, recent studies suggest that these patients fall frequently.[2,3]

Evidence has shown that the risk of falling in older adults is multifactorial, and balance[2] and postural control[4] impairments are important predictors of falls.[5] Thus, multi-component interventions including walking, balance and strength training have been recommended.[6] Pulmonary rehabilitation (PR) is an effective intervention for COPD which includes exercise training and psychoeducation to achieve the individual's maximum level of independence and function in the community.[7] However, this recommended standard of care is mainly focused on training peripheral muscles through endurance and strength training, and does not include a specific component of balance training. Although exercise has been shown to improve balance and decrease fall risk in older adults,[8] when the effect of PR on balance in patients with COPD was studied, minor improvements on balance were found.[9] The main aim of this exploratory study was to assess the effects of a PR program with a specific component of balance training on functional balance of patients with COPD.

Methods

Design and Participants

A one group pretest-posttest design was used. The study received full approval from the Institutional Ethics Committee. A convenience sample of outpatients with COPD was recruited in one primary care center. Inclusion criteria were diagnosis of COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD),[10] age ≥ 18 years old and clinical stability for 1 month prior to the study (i.e., no hospital admissions or exacerbations). Patients were excluded if they presented severe

psychiatric, neurologic or musculoskeletal conditions and/or unstable cardiovascular disease.

Eligible patients were informed about the study by general practitioners and 34 patients were contacted by the researchers. Before data collection, written informed consent was obtained.

Data Collection

Data on socio-demographic, fall history and lung function were obtained to characterize the sample. Fall history was assessed with a standardized question "*Have you had any falls in the last twelve months?*". Lung function was assessed with spirometry and the COPD grade was determined.[10] To assess the effects of the PR program, activities limitation resulting from breathlessness and health-related quality of life (HRQOL) were collected, followed by the assessment of quadriceps muscle strength, exercise tolerance and functional balance. All questionnaires and tests were administered before and after the PR program.

Intervention

The PR program was conducted for 12 weeks and included two main components: exercise training (3 times a week during 60 minutes each session) and psychoeducation (once a week during 90 minutes). The exercise training component comprised:

1. A warm up of 5-10 minutes including range-of-motion, stretching, low-intensity aerobic exercises and breathing techniques, such as pursed lips breathing, body positions, diaphragmatic breathing and airway clearance techniques.
2. Endurance training (walking) with a duration of 20 minutes at 60-80% of the average speed achieved during the six-minute walk test (6MWT). Training intensity

was adjusted according to patient's symptoms of fatigue and dyspnea (Modified Borg Scale 0-10).[7]

3. Strength training (15 minutes) included 7 exercises (2 sets of 10 repetitions) of the major upper and lower limbs muscle groups using elastic bands, free weights and ankle weights. The amount of weight was between 50-85% of the 10 repetition maximum (10-RM).[7] The training load was increased when the patient performed two additional repetitions with a given load on two consecutive sessions. The training intensity was adjusted as described in the endurance training.
4. Balance training during 5 minutes consisted of static and dynamic exercises using mainly upright positions. Balance exercises were organized in 4 levels:[6] i) postures that gradually reduced the base of support; ii) dynamic movements that perturbed the center of gravity; iii) stressing postural muscle groups; and iv) dynamic movements while performing a secondary task individually or in groups, with a progressively narrowed base of support. In this component, patients were also trained on how to lie down and get up from the floor.
5. A cool down of 10 minutes included similar exercises to the warm-up.

The psychoeducation component provided: information about COPD; healthy lifestyles; falls and fall prevention strategies; emotion-management strategies; problem solving techniques and community resources.

Primary Outcome Measure

The primary outcome measure was functional balance, which is defined as the ability to maintain equilibrium in dynamic situations required for daily activities. The Timed Up and Go (TUG) test was used to assess functional balance, as recent research has suggested that assessment of balance under multi-task conditions may be a more sensitive indicator of balance problems and falls than assessment of balance in a single-task context.[11] The test requires the patient to rise from a standard chair, walk 3

meters, turn around, walk back to the chair and sit down. Patients were instructed to walk quickly, but as safely as possible. Two TUG tests were performed and the best performance was considered. This test has been shown to predict falls in community-dwelling older adults[11] and normative reference scores are available.[12]

Secondary Outcome Measures

Activities limitation resulting from breathlessness was assessed by patients selecting the statement from the modified British Medical Research Council questionnaire (mMRC) that best described their limitation. HRQOL was assessed using the St. George's Respiratory Questionnaire (SGRQ) and a change of 4 units was considered clinically relevant.[13] Quadriceps muscle strength was assessed using the 10-RM with ankle weights. Exercise tolerance was measured using the 6MWT. Two tests were performed and the best performance considered.

Statistical Analysis

Descriptive statistics were used to describe the sample. Measurements collected before and after the PR program were compared using paired *t*-tests for normally distributed data, Wilcoxon signed-rank test for non-normally distributed data and ordinal data, and McNemar's test for dichotomous categorical data. Correlations between functional balance changes and changes in SGRQ total score, SGRQ symptoms score, quadriceps muscle strength and 6MWT were analyzed with Pearson's or Spearman's correlation coefficient. All statistical analyzes were performed using PASW Statistics version 18.0 for Windows (SPSS Inc., Chicago, Illinois) and graphs were created using GraphPad Software 5.0 (La Jolla, CA, USA).

Effect sizes (ES) were also determined to explore the degree to which the PR program was responsible for changes in activities limitation resulting from breathlessness, HRQOL, muscle strength, exercise tolerance and functional balance. Effect sizes were

calculated as the mean difference in values before and after PR divided by the mean standard deviation (i.e., mean standard deviation before and after PR) using G*Power Software 3.1.1 (Kiel, Germany). The magnitudes of the ES were interpreted as: ≥ 0.2 small effect, ≥ 0.5 medium effect and ≥0.8 large effect.[14] The level of significance considered was 0.05.

Results

A total of 34 patients enrolled in the study however, 12 (31.6%) dropped-out; due to: professional reasons (n=2), relocation (n=1), deterioration of health status due to muscular impairments (n=2), respiratory exacerbation (n=2), the person was submitted to a varicose vein surgery (n=1) and no reasons given (n=4). Therefore, 22 participants (13 males; 68.0±11.8 years old; forced expiratory volume in 1 second, FEV_1 72.2±22.3%predicted) completed the study. Regarding COPD severity, 9 patients had mild, 8 moderate and 5 severe to very severe COPD. Almost half of the participants (n=10; 45.5%) reported at least one fall in the preceding year. Table 1 provides the socio-demographic and clinical characteristics of the participants.

Table 1- Socio-demographic and clinical characteristics of the participants (n=22).

Characteristics	**Result**
Age (years)	68.0±11.8
Male	13 (59.1%)
BMI (Kg/m^2)	28.4±6.0
FEV_1 (% predicted)	72.2±22.3
GOLD classification	
Mild	9 (40.9%)
Moderate	8 (36.4%)

Severe to very severe	5 (22.7%)
Fall history	10 (45.5%)

Note: values show mean±SD or n(%) unless otherwise indicated. Abbreviations: BMI, body mass index; FEV_1, forced expiratory volume in 1 second.

A comparison of measures before and after PR is presented in table 2.

Table 2 - Effect of pulmonary rehabilitation on the activity limitation resulting from breathlessness, health-related quality of life, quadriceps muscle strength, exercise tolerance and functional balance (n=22).

Variable	**Pre-PR**	**Post-PR**	**Mean Change (95% CI)**	**p-value**	**ES**
mMRC	2.6±1.0	2.2±0.80	-0.5±0.9 (-0.8, -0.1)	0.025*	0.466
SGRQ total score	43.5±19.5	39.2±17.8	-4.3±11.0 (-9.3, 0.7)	0.089	0.391
10-RM quadriceps strength (kg)	3.2±1.7	6.3±2.2	3.1±2.1 (2.2, 4.0)	0.001*	1.475
6MWD (m)	375.8±94.9	411.4±97.0	35.7±34.7 (20.2, 51.0)	0.001*	1.027
TUG score (s)	8.9±2.3	7.2±1.7	-1.7±1.4 (-2.3, -1.1)	0.001*	1.249

Note. Values show as mean±SD or n(%). Mean change: Post-PR minus Pre-PR. Abbreviations: ES, effect sizes; mMRC, Modified British Medical Research Council questionnaire; SGRQ, St. George's Respiratory Questionnaire; 6MWD, six-minute walking distance; TUG, Timed up and go. *Significant at p-value<0.05.

After the PR program, the activities limitation resulting from breathlessness was significantly reduced (mean change -0.5; p=0.025; ES=0.466). The SGRQ total score did not change significantly (mean change -4.3 units; p=0.089; ES=0.391), although the change reached clinically relevance.[13] There was a significant improvement of the SGRQ symptoms score (mean change -12.2 units; p=0.012; ES=0.604), quadriceps muscle strength (mean change of 3.1Kg; p=0.001; ES=1.475) and exercise tolerance (mean change of 35.7 meters; p=0.001; ES=1.027).

Regarding the effect of PR on functional balance, the TUG score showed a significant improvement (figure 1) (mean change -1.7s; p=0.001; ES=1.249). Before PR, approximately half of the sample (n=9; 40.9%) and after PR, only 1 participant (4.5%) (p=0.008) had a TUG score worse than the average of age-matched healthy peers.[12]

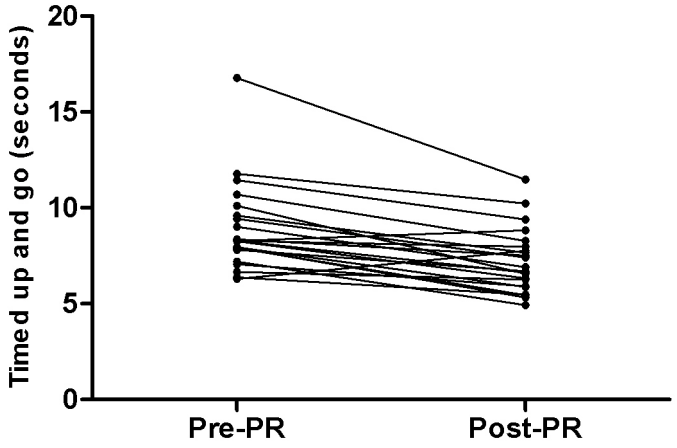

Figure 1: TUG score of the participants before and after the pulmonary rehabilitation (PR) program.

There were no statistically significant correlations between change in functional balance and change in SGRQ total score (r=0.171), SGRQ symptoms score (r=-0.018), quadriceps muscle strength (r=0.207) or six-minute walking distance (r=-0.060).

Discussion

The main finding of this study was that a PR program with a specific component of balance training had a large effect on functional balance improvements in patients with COPD.

Similarly to other studies, which have assessed the effects of PR on patients with COPD, significant improvements on activities limitation resulting from breathlessness, HRQOL, muscle strength and exercise tolerance were found. This shows that the implemented program was, overall, at least as effective as it has been previously reported. Regarding the effect of the program on patients' functional balance, a change of -1.7±1.4 seconds in TUG score was found. This result is slightly higher than the value obtained by Beauchamp et al. (-1.5±2.4 seconds).[9] In our study, the effect size for TUG test was much larger (ES=1.249) than in theirs (ES=0.625), indicating that a PR with a specific component of balance training may contribute to greater functional balance improvements than standard PR. However, this comparison must be carried out with caution, since the two studies included patients with different grades of the disease (FEV_1 72.2±22.3%predicted in the current study vs. 46.3±22.3%predicted in Beauchamp et al.[9]) and had different TUG protocols.

Even with the uncertainty that a PR program with balance training improves patients' functional balance into a greater extent than standard PR, our findings are clear in demonstrating that most participants with a TUG score worse than the average of their age-matched healthy peers at baseline,[12] achieved a normal TUG performance after the program. As TUG assesses balance under multi-task conditions and this is similar

to the performance of activities of daily living,[11] this result might be translated in less risk of falling.

Currently, it is not possible to determine if the TUG score improvement found in this study has or not clinical relevance, as TUG minimal detectable change (MDC) has not been determined for COPD. The MDC is the smallest amount of difference in individual scores between 2 points in time that represents a true statistical change. Therefore, we cannot firmly state that including a 5-minute component of balance training in PR programs is sufficient to promote clinically relevant functional balance improvements in patients with COPD. Nevertheless, in our study, balance training was implemented with the recommended frequency (3*week)[15] and incorporated static and dynamic exercises similar to everyday activities. Leung et al. (2013) assessed the effect of Short-form Sun-style Tai Chi compared to no exercise training on balance in patients with COPD. The intervention occurred during 12 weeks, twice a week with a duration of 60 minutes. It was observed that the Tai Chi group had a significant improvement in functional reach distance, compared to the control group (ES=1.45).[16] The distinct dose trainings between our study and the study from Leung et al. demonstrate the urgent need of guidelines about the optimal dose-response ratio of balance training.[6]

Limitations and Future Work

The dropout rate (31.6%) found in this study may be interpreted as an attrition bias. Nevertheless, it is in line with the dropout rates reported in other PR programs, between 20 and 40%.[17,18] The absence of a control group can also be seen as a limitation of this exploratory study; this should be considered in future studies.

As the intervention consisted of a multi-component PR program, the results on the TUG score cannot be interpreted as the result of the balance training component alone, but also related to the other components of the PR. Due to the difficulties in interpreting the clinical relevance of the data generated from the TUG score, in the future besides

determining the MDC for the TUG among patients with COPD, it is also recommended to use other measures especially targeted to assess the different components of balance to identify which of these components are impaired. Future longitudinal studies are also needed to determine the effectiveness of multi-component PR programs with balance training in reducing falls in COPD population.

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